UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------|-------------------------------|----------------------|---------------------|------------------|
| 10/679,714 | 10/06/2003 | Aziz Chafic Awad | Healthtreat 4.1-1 | 2884 |
| 21036 MCLEOD & M | 7590 05/13/200 IOYNE, P.C. | EXAMINER | | |
| 2190 COMMO | NS PARKWAY | THAKUR, VIREN A | | |
| OKEMOS, MI 48864 | | | ART UNIT | PAPER NUMBER |
| | | | 1794 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/13/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | |
|--|---|---|--|--|
| | 10/679,714 | AWAD, AZIZ CHAFIC | | |
| Office Action Summary | Examiner | Art Unit | | |
| | VIREN THAKUR | 1794 | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w. | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time. | J lely filed | | |
| Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | cause the application to become ABANDONE | O (35 U.S.C. § 133). | | |
| Status | | | | |
| 1) Responsive to communication(s) filed on 19 Fe 2a) This action is FINAL. 2b) This 3) Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | |
| Disposition of Claims | | | | |
| 4) ☐ Claim(s) 1,2,4,6-14 and 16-19 is/are pending in 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1,2,4,6-14 and 16-19 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or | vn from consideration. | | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the confidence Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examine 11). | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | |
| | animor. Noto the attached office | 7.00.001 01 101111 1 0 102. | | |
| Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/19/08. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ite | | |

Art Unit: 1794

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 19, 2008 has been entered.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1-2,4,6-14 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "adding a raw, uncooked food comprising asparagine and sugars comprising a fermenter..." It appears that this is an error, since the sugars cannot comprise a fermenter. The claim further recites the limitation "the fermented food containing an aqueous medium..." It is unclear as

Page 3

Art Unit: 1794

to whether the food is in an aqueous medium or whether the aqueous medium is contained within the food. Based on applicant's disclosure, it appears that the food is in an aqueous medium, however the claim appears to state that the food includes an aqueous medium. The claim further recites "an aqueous medium comprising added yeast extract for fermentation by a microorganism used for fermentations in the aqueous medium at a pH between about 4 and 8." This limitation is not clear as to whether the aqueous medium has a pH between about 4 and 8 or whether the food product has a pH between about 4 and 8.

Additionally, claim 4 recites the limitation "wherein the aqueous medium for the fermentation is at a temperature between about 10° and 40°C and a pH between about 4 and 5." The limitation is unclear as to whether this pH occurs prior to the fermentation or during fermentation.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. Claims 1-2, 6-10, 13-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilton et al. (US 4140801) in view of Christ et al. (US 4242361), "Yeast Growth Medium", "Catalogue of Bacteria & Bacteriophages", Champagnat (US 3193390), Lund (Detection of Microorganisms in Food), "Yeast Media, Solutions and Stocks", Christ et al. (US 4242361), Green et al. (US 3891771), Annuk et al. (US 5316776) and Sokolsky (US 1676166).

Regarding claim 1, Hilton et al. teach a process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, such as potatoes, comprising adding a raw uncooked food comprising asparagine and sugars to a fermenter (Column 7, lines 23-33). Hilton et al. further teach using an aqueous medium for fermentation by a microorganism (Column 3, lines 35-43). By fermenting the uncooked potatoes, Hilton et al. teach that the yeast used are "sufficient to lower the reducing sugar content of the potato solids during fermentation to an extent that they have improved resistance to browning during frying (Column 2, lines 39-43). As discussed in the previous Office Actions, although Hilton et al. do not specifically discuss the reduction of the formation of acrylamide, the Maillard reaction and its reactants have been well known (i.e. asparagine and reducing sugars). By

reducing one of the reactants, such as the reducing sugars, Hilton et al. inherently teach the reduction of the formation of acrylamide. This would further have been obvious to the ordinarily skilled artisan since Hilton et al. teach that upon frying the potato product has reduced browning and since the Maillard reaction, which results in the browning during frying would have been limited as a result of lowering the amount of one of the reactants. Hilton et al. teach that other components <u>may</u> be added, such as rice, tapioca or even raw potatoes or other pre-treated potatoes (column 5, line 66 to column 6, line 12). It is noted however that Hilton et al. teach that these are optionally added and thus do not require to be added to the fermented potato product. Therefore, it is noted that Hilton et al. teach wherein no sugar products are added to the potato through the frying step.

Claim 1 differs from Hilton et al. in specifically reciting wherein the aqueous medium comprises yeast extract.

Both Yeast Growth Medium and Cataloge of Bacteria & Bacteriophages have been relied on to teach that it has been well known in the art to use yeast extract for providing a nutrient medium for the microorganism. For example, on page 415 (#17) and 452 (#1006) of the Catalogue of Bacteria & Bacteriophages, media formulations teaches that yeast extract has been well known to be used in media for growth of bacteria. Additionally, Yeast Growth Medium and Yeast Media, Solutions and Stocks (Page 2 of 6 to 3 of 6) also teach the conventionality of using yeast extract as a growth media for Saccharomyces yeast. This is also supported by Champagnat, who teaches using yeast extract in combination with

other components to incubate a yeast strain (See column 3, line 37). Lund also provides evidence of the conventionality in using yeast extract as a nutrient components for a microorganism such as yeast (See Page 1765). Furthermore, it has been well known to the ordinarily skilled artisan that yeast and other microorganisms require nutrients in order to ferment a food. To therefore add yeast extract into the aqueous medium of Hilton et al., would have been obvious to one having ordinary skill in the art for the purpose of increasing the growth of the yeast or bacteria and thus enhancing the ability of the microorganism to ferment the food product.

Claim 1 further differs from combined teachings of the prior art in specifically reciting wherein the aqueous medium is at a pH between about 4 and 8. The Catalogue of Bacteria & Bacteriophages, for instance teaches that the aqueous media has a pH adjusted to 7 and 6.2 (See page 415 #17 and 452 #1006). These are the conditions for the media that are optimal for the growth of the bacteria strain. To therefore have a pH of between 4 and 8 would have been obvious and routinely determinable for the purpose of achieving the optimal growth conditions for the microorganism. Furthermore, to use a food grade acid to achieve the adjustment to between 4 and 8 would also have been obvious to the ordinarily skilled artisan, since the Catalogue of Bacteria & Bacteriophages (Page 452 #1006) teaches using food grade acids within the aqueous medium. Additionally, Christ et al. (Column 3, lines 37-40) teach using materials to adjust the pH of the solution to the desired level.

Art Unit: 1794

Claim 1 further differs from the combined teachings of the prior art in specifically reciting wherein the fermenter further comprises an outlet with a strainer for straining the fermented food and further wherein the aqueous medium is agitated in the fermenter. Regarding the strainer, it is noted that Christ et al. teach recycling of a fermentation medium which comprises a microorganism (Column 3, lines 29-40). As a result, the food at the top of the fermenter is also rehydrated with the fermentation medium, thus ensuring more uniform fermentation of the entire batch (column 1, line 68 to column 2, line 2 and column 2, lines 5-11). Green et al. has been relied on to teach using a strainer in a recycling type of an apparatus (Figure 2, item 12 and column 2, lines 65-68). As a result of the screen, the brine is capable of being recirculated, while the food is retained in its position within the vessel. Nevertheless, since Christ et al. teach fermenting a food product using a microorganism, and further teach that any vegetable material can be fermented in the apparatus (Column 3, lines 9-12), it would have been obvious to have used a screen or some form of a straining apparatus for the purpose of preventing the food material from being up taken through the recycling stream. To therefore use a strainer to prevent the food of Christ et al. from being taken up through the recycle stream would have been obvious to one having ordinary skill in the art.

Regarding agitation, it is noted that Hilton et al., teach wherein the fermentation microorganism and the food product can be effectively mixed so that the fermentation progresses at a satisfactory rate (Column 2, lines 44-47). To therefore use agitation would have been obvious since the prior art

Art Unit: 1794

recognized that mixing further facilitates the rate of fermentation. Nevertheless, Annuk et al. (US 5316776) has also been relied on to teach that it has been conventional in the art to use an agitating means for the purpose of achieving homogeneity in the fermentation (Column 10, lines 52-56). Since Hilton et al. teach mixing and since Annuk et al. teach agitating the mixture to achieve homogeneity in the fermentation, it would have been obvious to one having ordinary skill in the art to agitate the aqueous medium for the purpose of achieving homogeneity in the fermentation.

Claim 1 further differs from the combination of the prior art in reciting removing the aqueous medium through the outlet strainer. This has been addressed above with respect to the Green et al., and Christ et al. references.

Claim 1 further differs from the combination of the prior art in specifically reciting wherein the food is washed in the fermenter by introducing water to remove residues on the food. Sokolsky has been relied on to teach that after fermentation, a food product contains residues which would be desired to be washed off (Page 1, lines 31-38). Since Hilton et al. teach that the flavor of the potatoes after frying should have good flavor and other characteristics (Column 6, lines 50-52) it would have been obvious to remove any residual bacteria and fermentation medium that remain on the potato, which would alter the final flavor of the product. This further would have been obvious since Sokolsky teaches that washing a fermented product to remove any residual bacteria has been conventional in the art.

Regarding claim 6, Hilton et al. teach frying the food (column 6, line 50).

al. teach using yeast.

Regarding claim 7, Hilton et al is silent in specifically teaching wherein the food can be baked, however it has been well known in the art to bake potato products, such as French fries in an oven. To therefore bake a potato based product would have been obvious to one having ordinary skill in the art.

Regarding claim 8, Hilton et al. teach making potato chips and French fries

(column 5, lines 46-50). Regarding claim 9, Hilton et al. is silent in teaching recirculating the aqueous medium into and out of the vessel, however, Christ et al. and Green et al., as discussed above, address recirculating the aqueous medium while retaining the food in the fermenter. Regarding claim 10, Hilton et

Regarding claim 13, the combined teachings of Hilton et al., and Christ et al. teach recycling the microorganism, since the fermentation medium is recycled and the unused yeast would also have been recycled. To remove fermented food product and then recycle the microorganism would have been obvious to the ordinarily skilled artisan for the purpose of making a more efficient process.

Regarding claim 14, Hilton et al, in combination with the teachings of the Catalogue of Bacteria and Bacteriophages teaches adjusting the pH of the aqueous medium prior to fermenting. In this case, the media for growing the bacteria, has been adjusted.

Regarding claim 17, Hilton et al. teach drying the food after fermentation and before cooking (column 2, lines 19-27). Claim 18 differs in specifically reciting wherein the water is distilled. The Catalogue of Bacteria & Bacteriophages teaches media for the growth of bacteria wherein distilled water

is used (page 415 #17). Even further however, using purified water would have been obvious to the ordinarily skilled artisan to ensure that impurities or other microorganisms which may be present in the water do not contaminate the food and the fermentation process. Since it would have been obvious to the ordinarily skilled artisan that the fermentation media and the nutrients in the media directly affects the fermentation rate, to minimize the impurities by using distilled water would have been obvious.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-2, 6-10, 13-14 and 17-19, above, and in further view of "Yeast Fermentation" and as further evidenced by "How To Restart a Stuck Fermentation."

Hilton et al. teach that the product is fermented in an aqueous medium at 29°C (column 7, line 30). Claim 4 differs from the combination of the prior art in specifically reciting wherein the pH is between about 4 and 5. "Yeast Fermentation" teaches that the pH of the fermentation will be controlled at pH 5 (see page 2 of 5 - Experimental Conditions). "How To Restart a Stuck Fermentation" is cited as further evidence of the conventionality of that the ideal condition for yeast fermentation are between 3.5 to 5.5 (See page 1). To therefore have a pH of 5 at the start of the fermentation would have been obvious to the ordinarily skilled artisan, since Yeast Fermentation teaches that this pH is optimum for yeast growth.

8. Claims 4, 11, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-2, 6-10, 13-14 and 17-19, above, and in further view of Hagiwara (US 4298620), Bechtle (US 3818109), "Microbiology and Bacteriology", "Fermented Fruits and Vegetables", Baldwin (US 2744017), applicant's admission of the prior art and "Lactic Acid Bacteria".

Page 11

Hilton et al. teach that the product is fermented in an aqueous medium at 29°C (Column 7, line 30). Claim 4 differs from the combination of the prior art in specifically reciting wherein the pH is between about 4 and 5.

Hagiwara teaches that lactic acid bacteria fermentation using lactobacillus bacteria, wherein the pH of the culture medium has been known to be between about 4 and 6 at the start of fermentation (column 4, lines 53-60). Therefore, Hagiwara teaches that it has been conventional in the art have a culture medium for lactic acid bacteria at a pH of 4 at the start of the fermentation.

Bechtle also teaches fermentation using lactic acid bacteria such as lactobacillus, Streptococcus and Leuconostoc (column 5, lines 60-64) and further teach that the fermentation culture at the start of the fermentation medium has been known to be between 4 and 5, such as at 4.9 (Column 7, line 43). To therefore have a culture medium having a pH of 4 would have been obvious to one having ordinary skill in the art, when using lactic acid bacteria for the fermentation.

Art Unit: 1794

Microbiology and Bacteriology has been cited as further evidence that it has been well known in the art that lactic acid bacteria to grow in a fermentation medium at pH of 4.4 (See chapter 12-1).

Claims 11 and 12 differ from the prior art in specifically reciting wherein the microorganism is a bacterium and wherein said microorganism is a lactic acid producing microorganism. As admitted by applicant on page 2, paragraph 0003, lines 4-5, the use of acid production bacteria cultures for food fermentation is well known. The prior art to Hagiwara and Bechtle teach that it has been well known in the art to use lactic acid bacteria for foods. Christ et al., teach using yeast in the fermentation for producing sauerkraut. Fermented Fruits and Vegetables, also teaches that it has been well known in the art to use lactic acid bacteria for fermentation in the production of sauerkraut (See page 6 of 13, See Section 5.6.2). Baldwin has also been cited to teach that it has been known in the art to use lactic acid bacteria for the purpose of reducing "Maillard Type" browning (column 1, lines 27-35 and lines 39-49). Baldwin teaches in the cited column and lines that fermentation using lactic acid bacteria removing naturally occurring glucose. To therefore use lactic acid bacteria, would therefore have been obvious to one having ordinary skill in the art, since the prior art teaches that it has been conventional to ferment foods using lactic acid bacteria.

Claim 16 differs from the combination in specifically reciting wherein the pH of the aqueous medium at the end of the fermentation is between about 4 and 5. Hagiwara teaches that by using lactic acid bacteria, at the end of the fermentation the pH of the culture medium is about 4 (Column 4, line 58).

Art Unit: 1794

Hagiwara provides further evidence of the conventionality, when using lactic acid bacteria, for the aqueous medium to be acidic, such as at a pH of 4, since the result of lactic acid bacterial fermentation is the production of lactic bacteria, a low pH substance. This is further evidenced by "Lactic Acid Bacteria" who teach that lactic acid bacteria product lactic acid, which results in the pH dropping to as low as 4.0 (see background, third paragraph).

Response to Arguments

9. On pages 9 to 10, applicant discusses the differences between enzymatic browning, such as that of blanching and non-enzymatic browning, which results in the Maillard reaction. It is noted that in the Final Office Action, mailed October 18, 2007, the point that the examiner attempted to make is that Hilton et al. teach that other components <u>may</u> be added after fermentation of the potato products (column 6, lines 7-12). It is noted that Hilton et al. also state that other types of solids <u>can</u> be included in the fermented potato, such as "raw potatoes which may be blanched or otherwise pretreated or partially or totally dehydrated or even a minor amount of postfermented highly dehydrated potato solids" (Column 5, line 66 to column 6, line 3). This teaches that these other ingredients are not required but can optionally be included in the fermented potato products. This was in response to applicant's arguments on pages 9-10 of the response mailed August 6, 2007.

Art Unit: 1794

10. Applicant's arguments on page 14 of the response with respect to the Baldwin reference are moot in view of the grounds for rejection above. As noted by applicant, the use of lactic acid bacteria has been well known in the art for fermenting foods. Nevertheless, the newly cited references, as discussed in the rejections above, further provide evidence of the conventionality of using lactic acid bacteria for the purpose of fermenting food products and changing the pH of the fermentation medium. Nevertheless, it is noted that the Baldwin reference has only been relied on to teach that it has been well known in the art to use lactic acid bacteria for the fermentation of a food product and also, the Baldwin reference recognized that fermentation with lactic acid bacteria removes the naturally occurring glucose which is responsible for Maillard browning reaction.

Page 14

11. Applicant's arguments on page 14 that it would not have been obvious to one having ordinary skill in the art to have employed a pH pre-adjusting step in conjunction with the removal of acrylamide precursors since the cited art and motivation for doing so is not suggested have been considered but is not deemed persuasive. It is noted that the newly applied references teach that it has been conventional in the art to use yeast and lactic acid bacteria with a fermentation medium having a low pH. Even further, however, the claims reciting the adjustment of the pH prior to fermentation are still broad. For instance, claim 14 recites the adjustment of the pH prior to the fermentation, however, claim 1 recites a pH of between 4 and 8. The newly cited references teach that the pH

Art Unit: 1794

can be adjusted to within this range for the purpose of achieving the desired fermentation.

12. It is further noted that applicant's invention only differs from the Hilton et al. reference in the manner by which the fermentation is carried out. That is, using a recirculating system. Nevertheless, the newly applied references teach that a recirculating fermenting system has been conventional in the art and further that such systems have been conventional in fermenting food products. Applicant's invention further appears to differ based on the type of microorganism used to perform the fermentation, and the conditions of the fermentation medium. The prior art has also taught that it has been conventional to use both yeast and bacteria, such as lactic acid bacteria to ferment food products. Lactic acid bacteria has also been known to remove components that produce the Maillard reaction. Additionally, the cited references also teach that it has been conventional for the starting pH of a fermentation medium for both lactic acid bacteria and yeast to be between 4 and 5. Therefore, applicant's claimed invention is still considered obvious over the combination of references as discussed above.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 1794

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VIREN THAKUR whose telephone number is (571)272-6694. The examiner can normally be reached on Monday through Friday from 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571)272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. T./ Examiner, Art Unit 1794 /Steve Weinstein/ Primary Examiner, Art Unit 1794